PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Schaller, *et al.*

Examiner: Nihir B. Patel

Serial No.: 09/828,322

Group Art Unit: 3743

Filing Date: April 05, 2001

Docket No.: P-21814.00

Title: BRIDGE CLIP TISSUE CONNECTOR APPARATUS AND METHODS

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8: I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop After Final, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 19th day of March, 2007.

Signature

Jo L. Brecht

Printed Name

ON APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

ARGUMENTS ACCOMPANYING
PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Appellants request review of the final rejection of claims 1-26 and 31-55 in the above-identified application. These claims, as they appear in the Listing of the Claims on pages 2-9 of the Amendment and Response filed June 8, 2006, were rejected in the Final Office Action mailed September 25, 2006.

The following Arguments, beginning on page two (2), accompany the attached Pre-Appeal Brief Request for Review. No Amendments are being filed with these Arguments.

Independent claim 1 recites "[a] tissue connector assembly comprising a surgical **fastener** comprising two **clips**, each sized and shaped to attach tissues and hold the tissues together therein, and a **bridge portion** connecting said two clip and spacing clips from one another." Drawings from the application showing one possible form of the present invention are shown above. Independent claim 20 recites"[a] tissue connector assembly comprising: a surgical **fastener** comprising two **clips** sized and shaped to attach tissues and hold the tissues therein including at least one self-closing clip having an open configuration and a closed configuration, where said open configuration is a biased configuration and said closed configuration is an unbiased configuration, and a **bridge portion** having a substantially straight portion connecting said two clips; and release mechanism having a first position to bias said self-closing clip in said open configuration, and a second position to unbias said self-closing clip into said closed configuration." Additional independent claims are present.

The September 25, 2006 Final Office Action rejected claims **1-14, 20-23, and 31-35** under 35 U.S.C. §102(b) as being anticipated by Wallace *et al.*, (U.S. Patent No. 5,941,888 hereinafter "the `888 patent"). The Office Action alleged the `888 patent "teaches a tissue connector assembly comprising two clips **102 and 104** each is sized and shaped to attach tissues and hold the tissue together therein, and a bridge portion **106** connecting the two clips and spacing the clips from one another. **(see figure 1).**" (Office Action, 09/25/06, p. 2, ¶ 3).

The '888 patent discloses an occlusion device. The '888 patent is devoid of any suggestion that the occlusion device can serve as a tissue connector assembly or fastener. The occlusion device has one or more vaso-occlusive members that are connected by electrolytically disintegratible links. Referring to FIG. 1, electrolytically disintegratible link 106 is shown between vaso-occlusive members 102 and 104, which are shown in the form of coils. The coils may be formed so that they are essentially linear as they pass through a delivery catheter and then assume a randomly oriented relaxed condition after they are released from the catheter (col. 5, lines 49-54).

In the Office Action dated December 8, 2005, it was advanced that the '888 patent's vaso-occlusive member is capable of connecting two tissues based on a hypothetical illustration provided in the Office Action and designated Figure 1. Appellants respectfully submit that generation of a hypothetical Figure and speculating that it is a Figure from the patent application is serious error. The Final Office Action reaffirmed the use of the hypothetical illustration as

part of the rejection. See page 10 of the Final Office Action. Appellant again respectfully points out that said Figure 1 is the Examiner's hypothetical drawing and is not present in the '888 patent and therefore should not form a basis for a rejection under 35 U.S.C. 102.

Further, it is not clear how the catheter in the '888 patent can get stuck in the openings of two aneurysms as hypothetically set forth in the Office Action. For example, the distal end of the '888 patent catheter only appears to be capable of entering one aneurysm opening after which the occlusive device is deployed, the disintegratible link electrolytically disintegrated, and the catheter withdrawn. It does not appear possible to have the catheter simultaneously extend into two aneurysm openings as shown in the Office Action hypothetical. That is, although the drawing shows the catheter distal end extending into one aneurysm opening and the catheter proximal end extending into the opening of the other aneurysm, this deployment does not appear possible. Even if it were, '888 patent certainly could not have intended that the catheter be left behind and permanently implanted in the patient. Also '888 patent certainly did not intend that the catheter and occlusive device be positioned as shown in the Examiner's hypothetical drawing where they obstruct the vessel lumen and could create serious complications.

Applicants also note that the hypothetical drawing in the Office Action does not account for how the disintegratible link, which was electrically connected to power supply 518, was positioned prior to electrolytic disintegration thereof to release the occlusive members. This further raises doubt as to the possibility of the catheter and occlusive device being positioned as shown in the Examiner's hypothetical.

The `888 patent merely discloses the "embolism-forming device which may be introduced into an aneurysm using endovascular placement procedures" and "a vascular occlusion member assembly in which multiple vaso-occlusive devices can be selectively detached via multiple electrolytically disintegratible links." (Col. 2, ll. 8-10, and Col. 3, 42-45 respectively). "Because of the unique design of the present invention, the appropriate length vaso-occlusive member or members can effectively be selected by the physician without removal of the delivery wire from the delivery catheter." (Col. 4, ll. 29-33). This does not disclose that the vaso-occlusive member assembly can act as a tissue connector assembly or comprises clips.

Further, the September 25, 2006 Final Office Action does not apply the `888 patent appropriately to reject the claims of the current application. For example, in the paragraphs:

3. **As to claim 1,** Wallace teaches a tissue connector assembly comprising two clips **102 and 104** each is sized and shaped to attach tissues and hold the tissue together therein, and a bridge portion **106** connecting the two clips and spacing the clips from one another **(see figure 1).** **********
9. **As to claim 7,** Wallace teaches an apparatus that further comprises a coil surrounding a substantial length of the closing clip **(see figure 1).**

In paragraph 3, the Office Action posits reference items **102 and 104** disclose clips. Items **102 and 104** do not disclose clips. They are vaso-occlusion members so designed to form emboli. (see `888 patent generally).

The Office Action in paragraph 9 posits reference item **106** discloses a clip. Item **106** does not disclose a clip. It is an "[e]lectrolytically disintegratible link **106**" that is "preferably bare and relatively more susceptible to electrolysis." (Col. 5, ll. 55-57). It is respectfully submitted that interpreting an electrolytically disintegratible link to be appellant's claimed clip would be unreasonable.

Appellants further respectfully submit it is unreasonable to equate emboli forming members or electrolytically disintegratible links to surgical clips. The Office Action committed error when it defined these reference elements as described above and applied them against Appellant.

Additionally, the `888 patent fails to disclose an unbiased configuration of the vaso-occlusive member possessing the ability to function as a surgical fastener. The `888 patent discloses a winding pitch configuration for elements **102 and 104** "equal to the diameter of the wire used in the coil" variable to a configuration that "assume[s] a randomly oriented relaxed condition after they are released from the distal end of the catheter." (Col. 5, ll. 23-54).

The winding disclosure does not support the vaso-occlusive member possesses the ability to function as a tissue connector assembly. It does not disclose a tissue connector assembly as claimed in the current application and as depicted above.

Appellant believes the claims are in condition for allowance and respectfully requests withdrawal of the102(b) rejection.

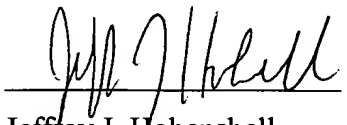
The Final Office Action rejected claims **15-19, 24-26, 36-38, and 35** under 35 U.S.C. §103(a) as being unpatentable over Chervitz *et al.* in view of the `888 patent. Chervitz et al does not disclose or suggest tissue piercing members that are releasably coupled to the device of Chervitz et al. as set forth in Applicant's claims 15 and 24. Chervitz et al. discloses that needles

12 are permanently secured to suture body 11 (see Col. 2, lines 44-47 where it states that the needles are connected to the suture body by swaging, adhesive or the like). In contrast, Applicant's claimed apparatus has tissue piercing members releasably coupled to a fastener and needs not require cutting or breaking to remove the piercing members.

If the needles in Chervitz et al. were releasably attached or coupled to the suture, they would not need to be "cut" or "broken" to disconnect them from the device; the coupling simply could be released. To interpret the "releasably" attached or "releasably" coupled claim language otherwise would be tantamount to saying that two pieces of steel that are welded together are "releasably" coupled to one another because the weldment could be cut with cutting tools. Certainly, this argument is not reasonable. To interpret "releasably coupled" to be the same thing as "coupled" is improper because it gives no weight or meaning to the term "releasably."

The `568 patent discloses an expandable body suture, incorporating needles designed for removal and disposal after placement of the suture. The suture contains an "enlarged section, pledget, or the like". (Col. 1, ll. 38-47). Often the diameter of the suture and needle junction is larger than the diameter of the suture alone, resulting in a loosely fitting suture. (Col. 1, ll. 16-18). The invention of the `568 patent is a suture containing a pledget designed to fill the hole created by passing a needle/suture through tissues such as bone, tendons, and ligament. (Col. 1, 38-47).

The `888 patent is described above. These are utterly different devices. An expandable body suture, incorporating disposable needles is completely unrelated to a vaso-occlusive device, with a plurality of members separated by electrolytically disintegratible links. For example, the needles of the '568 would not be left in the body as an implant. They are separated from the remainder of the assembly and disposed of. There is no suggestion that one skilled in the art would look to the vaso-occlusive device elements (as found in the `888 patent) to modify the expandable body suture (as found in the `568 patent) to create a tissue connector assembly as claimed in the current application.



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March 16, 2007